INSTRUCTIONS FOR USE

RegenePro[™] Collagen Wound Dressing

STERILE

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Intended Use

RegenePro[™] Collagen Wound Dressing is indicated for the management of oral wounds and sores including:

- periodontal surgical wounds
- surgical wounds and traumatic wounds
- suture sites
- oral ulcers (non-infected or viral)
- denture sores
- burns

Product Description

RegenePro[™] Collagen Wound Dressing is a soft, white to off-white, resorbable collagen dressing produced using purified Type I collagen derived from bovine Achilles tendon. The thickness and pore structure of the device allow it to absorb fluid and blood at the defect site. Upon hydration and after manipulation during placement the thickness of the dressing will reduce.

Directions for Use

Using sterile gloves or instruments, remove RegenePro[™] Collagen Wound Dressing from its packaging (pouch or tray).

- The wound should be rinsed and excess fluid removed.
 If required, RegenePro[™] Collagen Wound Dressing can be hydrated with saline solution before application.
- RegenePro[™] Collagen Wound Dressing should be placed into or over the wound and held in place until adherence has been achieved. RegenePro[™] Collagen Wound Dressing can be left *in situ*; suture as appropriate to minimize movement.
- RegenePro[™] Collagen Wound Dressing may be replaced if it falls off the wound prematurely. Replacement after premature removal of RegenePro[™] Collagen Wound Dressing is at the clinician's discretion.

Contraindications

RegenePro[™] Collagen Wound Dressing is contraindicated in patients who have acute infections and in the treatment of contaminated wounds in the oral cavity.

RegenePro[™] Collagen Wound Dressing should not be used on patients with known sensitivity or allergy to bovine proteins.

Large tissue defects should not be filled with several layers of RegenePro[™] Collagen Wound Dressing. RegenePro[™] Collagen Wound Dressing is not intended for use as a bone void filler.

Precautions

RegenePro[™] Collagen Wound Dressing should not be used when visible signs of infection are present in the wound area.

Discontinue use if excessive redness, pain, swelling or blistering occurs.

The contents of each pack are considered sterile unless opened or damaged.

Do not use if individual packs are damaged or opened.

Prior to use, check the use by date printed on the packaging.

Single use only.

Do not resterilize.

How Supplied

RegenePro[™] Collagen Wound Dressing is supplied sterile, non-pyrogenic and for single use only.

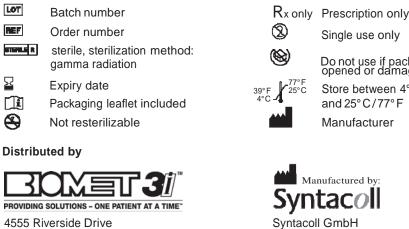
Product Sizes

Sponge: 36mm x 18mm Plug: Bottom: Ø14mm, Top: Ø10mm, Height: 17mm.

Storage

RegenePro™ Collagen Wound Dressing should be stored away from direct sunlight. Store between 4° C/39° F and 25° C/77° F.

Explanation of Symbols



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Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist